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Editor's Choice – Re-interventions After Repair of Ruptured Abdominal Aortic Aneurysm: A Report From the IMPROVE Randomised Trial

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WHAT THIS PAPER ADDS

The mid-term re-intervention rate after ruptured abdominal aortic aneurysm repair by endovascular or open repair appears to be twice as high as after elective repair. This suggests the need for bespoke surveillance protocols after rupture. Limb ischaemia is a frequent early reason and distal aneurysms a frequent later reason for re-intervention to indicate where quality improvement programmes might be directed. Limb amputation is uncommon but higher after open repair than after endovascular aneurysm repair.

Objective/Background: The aim was to describe the re-interventions after endovascular and open repair of rupture, and investigate whether these were associated with aortic morphology.

Methods: In total, 502 patients from the IMPROVE randomised trial (ISRCTN48334791) with repair of rupture were followed-up for re-interventions for at least 3 years. Pre-operative aortic morphology was assessed in a core laboratory. Re-interventions were described by time (0–90 days, 3 months–3 years) as arterial or laparotomy related, respectively, and ranked for severity by surgeons and patients separately. Rare re-interventions to 1 year, were summarised across three ruptured abdominal aortic aneurysm trials (IMPROVE, AJAX, and ECAR) and odds ratios (OR) describing differences were pooled via meta-analysis.

Results: Re-interventions were most common in the first 90 days. Overall rates were 186 and 226 per 100 person years for the endovascular strategy and open repair groups, respectively ($p = .20$) but between 3 months and 3 years (mid-term) the rates had slowed to 9.5 and 6.0 re-interventions per 100 person years, respectively ($p = .090$) and about one third of these were for a life threatening condition. In this latter, mid-term period, 42 of 313 remaining patients (13%) required at least one re-intervention, most commonly for endoleak or other endograft complication after treatment by endovascular aneurysm repair (EVAR) (21 of 38 re-interventions), whereas distal aneurysms were the commonest reason (four of 23) for re-interventions after treatment by open repair. Arterial re-interventions within 3 years were associated with increasing common iliac artery diameter (OR 1.48, 95% confidence interval [CI] 0.13–0.93; $p = .004$). Amputation, rare but ranked as the worst re-intervention by patients, was less common in the first year after treatment with EVAR (OR 0.2, 95% CI 0.05–0.88) from meta-analysis of three trials.

Conclusion: The rate of mid-term re-interventions after rupture is high, more than double that after elective EVAR and open repair, suggesting the need for bespoke surveillance protocols. Amputations are much less common in patients treated by EVAR than in those treated by open repair.

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INTRODUCTION

As experience with elective endovascular aneurysm repair (EVAR) of abdominal aortic aneurysm (AAA) has increased and stent graft technology has advanced, the rate of re-interventions has reduced. In the early randomised trials, the mid-term re-intervention rates were about 3.5 per 100 person years versus 0.5 per 100 person years after open repair,[1] but, today, much lower rates are reported from more recent data.[2] Endovascular repair of ruptured AAA

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presents additional challenges: the aneurysms are larger, the emergency imaging may not be optimal, sizing for endografts may be difficult owing to hypotensive arterial collapse, the available stock of endografts may be limited and these may be used outside conservative instructions for use (IFU). Therefore, there is widespread acceptance that EVAR for rupture is likely to be associated with a higher re-intervention rate than EVAR for elective repair.

There are few studies that report mid-term re-intervention rates after either EVAR or open repair for rupture. The most comprehensive study comes from the 467 patients with repair of ruptured AAA in the Amsterdam cohort from 2004 to 2011.[3] By 5 years 45% of the EVAR patients and 40% of the open repair patients had had at least one re-intervention. The re-interventions in the primary admission and after discharge were described separately. After discharge the rate of re-interventions after EVAR was nearly four times as high as after open repair and a common reason for re-intervention after EVAR was life threatening graft infection.

The IMPROVE trial, which randomised 613 patients with a clinical diagnosis of ruptured AAA to either an endovascular strategy (EVAR if morphologically feasible, open repair if not) or open repair, included 502 patients in whom repair of rupture was commenced, and followed these patients for re-interventions for 3 or more years. It has already been reported that the overall re-intervention rates were not significantly different between the randomised groups and that any additional re-interventions incurred in the endovascular strategy group did not compromise the overall cost-effectiveness of the endovascular strategy.[4] The purpose here is threefold: (i) to provide further insight concerning the reasons for and rates of re-intervention (directly aneurysm related and other) in the 502 patients with repair of rupture started, both by randomised group and by treatment received; (ii) to investigate whether pre-operative aneurysm morphology was associated with re-intervention rates; and (iii) to assess whether major amputation (an uncommon outcome but one much feared by patients) was more common after either EVAR or open repair in an individual patient meta-analysis across the three recent European randomised trials for the management of ruptured AAA.[5–7] The first two aims will also provide important information as to whether surveillance protocols after rupture might need to be different from those after elective AAA repair.

METHODS

The design and patients of the IMPROVE trial (ISRCTN48334791), their follow-up, and assessment of baseline aortic morphology have been described previously.[8,9] Briefly, 613 patients with an in hospital clinical diagnosis of ruptured AAA were randomised to either an endovascular strategy (immediate computed tomography [CT] scan and EVAR if morphologically feasible, otherwise open repair) or to open repair (CT scan optional). Of these, 502 patients with a confirmed diagnosis of rupture had aneurysm repair or started aneurysm repair and were followed up by trained local coordinators, for all re-interventions in the first 30 days, and aneurysm related re-interventions for 3 years thereafter. The trial protocol required clinical follow-up with imaging at 3, 12, and 36 months after repair, with intermediate follow-up left to the discretion of each trial centre. A standardised protocol for the detection and management of abdominal compartment syndrome, with recording of intra-abdominal pressures, was recommended but not widely followed. The completeness of re-intervention data, including re-interventions at non-trial hospitals, was verified by cross-checking against an administrative data set for English patients (Hospital Episode Statistics) and by detailed audit for Scottish and Canadian patients. Re-interventions beyond 3 years were not collected comprehensively. Re-interventions for pre-existing conditions, for example colon cancer, which had been included for the analysis of outcomes at 30 days are excluded from the present analysis, whereas fistula formation to treat renal failure and endovascular treatment of pulmonary embolism are included. Trial investigators extended the categorisation of re-interventions used by the EVAR-1 trial to obtain a consensus as to whether a re-intervention was for a life threatening condition (Table S1 [see Supplementary Material], with a full list of re-interventions).[1] Two observers categorised the re-interventions as arterial, laparotomy related, or other, with differences resolved by discussion. Separately, six patients or their spouses, from outside the trial, were asked to rank the main re-interventions: they were unanimous in reporting amputation of the leg as the most feared re-intervention, followed by graft infection.

The indications for re-intervention are tabulated both by randomised group and by treatment received. When two separate indications for re-intervention were corrected in the same operating or endovascular session these are listed separately but described in table footnotes. Multiple planned recurring procedures requiring time in the operating theatre (e.g., debridement, change of dressings) are excluded from the descriptive tables (e.g., there would be only a single listing for change of negative pressure wound therapy dressing, even if this occurred on several occasions).

CT scans were acquired in DICOM format from hospital archives, anonymised, and transferred to the core laboratory at St George's Vascular Institute for three dimensional reconstruction and analysis[10]; in total, 458 admission scans from patients with confirmed rupture were available.[11] Five morphological parameters (aortic diameter at 1 mm distal to the distal renal artery, aneurysm neck length from distal renal artery to sac, proximal neck angle α, maximum aneurysm diameter, and maximum common iliac diameter) were measured in a core laboratory and a sixth, neck conicality derived, as described previously.[11] From these parameters the endovascular repairs were categorised as either within liberal IFU or not (liberal IFU aneurysm neck length $\geq$ 10 mm, neck diameter $\leq$ 32 mm, and neck angle $< 60^{\circ}$).[12] The 3 month follow up CT scans also were collected in the core laboratory and were used to confirm the diagnosis of any underlying conditions requiring re-intervention at this time. Individual patient data for baseline characteristics and follow-up to 1 year were also

available through a collaboration with the other two recent European trials for ruptured AAA, AJAX and ECAR.[13,14]

Ethical approval for the IMPROVE trial was from South-Central Berkshire Research Ethics Committee 08/H0505/173 (England and Wales), Scotland A Research Ethics Committee 08/MRE00/90 (Scotland), and the University of Western Ontario Health Sciences Research Ethics Board 17698 (Canada).

Statistical analyses

The analyses were conducted according to pre-specified analysis plans. Rates of re-intervention were analysed on an intention to treat basis and were not adjusted for baseline variables. As previously, missing data for baseline variables were imputed before analysis using chained equations.[15]

For the analyses of associations with morphological parameters, Cox regression multiple failure time models were fitted adjusting for pre-specified confounders (age, sex, Hardman index lowest recorded systolic blood pressure, randomised group, and treatment commenced).[16,17] A further model additionally adjusted the estimates for the effect of all the other morphological variables. For the IFU analysis, hazard ratios, 95% confidence intervals (CIs) and p values (calculated using Wald's test) are presented. Each of the six morphological variables were considered as continuous covariates and odds ratios (ORs) are reported based on a 1 SD increase to allow fair comparison of their relative importance.

For the meta-analysis of amputations in AJAX, ECAR, and IMPROVE, primary analyses considered amputation according to the groups "as randomised" within each trial, irrespective of the different trial designs and secondary analyses considered amputation following treatment received. The timing of amputation was assessed from randomisation (for IMPROVE) and from hospital admission (for AJAX and ECAR). The OR of amputation for endovascular repair (or endovascular strategy) versus open repair for each trial was estimated and together were pooled using fixed effect meta-analysis using a continuity correction of ½ to trials with zero events. The proportion of between trial variability beyond that expected by chance was quantified using the I^2 statistic.[18]

All analyses were conducted using Stata statistical software, version 12 (StataCorp., College Station, TX, USA).

RESULTS

Of the 502 patients with repair of rupture started 259 had been randomised to an endovascular strategy and 243 to open repair; 182 patients commenced EVAR and 320 commenced open repair. The two groups were well matched for baseline characteristics.[4] The endovascular strategy group had a mean age of 76.0 years, 50 were women and the mean AAA diameter was 8.7 cm: 75 (29%) required at least one re-intervention. The open repair group had a mean age of 76.2 years, 48 were women, and the mean AAA diameter was 8.4 cm: 66 (27%) required at least one re-intervention. The overall re-intervention rates were similar in the endovascular strategy and open repair groups at 26.0 and 28.4 re-interventions per 100 person years, respectively ($p = .52$). Similarly, the overall rate of re-interventions for life threatening conditions was similar between the two groups at nine and 11 re-interventions per 100 person years, respectively ($p = .29$).

The listing of indications for re-intervention are shown separately for the acute period (0—90 days), the mid-term (3 months—3 years), and available information for beyond 3 years in Tables 1—3, respectively, both by randomised group and by treatment received.

Re-interventions in the first 90 days

In the first 90 days, the re-intervention rates were high at 186 and 226 per 100 person years for the endovascular strategy and open repair randomised groups, respectively ($p = .20$). Re-interventions for life threatening conditions were slightly, but not significantly, more common in both those randomised to open repair and those treated by open repair. The commonest indications for re-intervention were bowel ischaemia and limb ischaemia, both of which were more common in patients who received open repair. After initial resolution of abdominal compartment syndrome, later resection for bowel ischaemia occurred in three patients (two EVAR, one open repair). There were only two cases of graft infection, both in the femoro-femoral cross-over graft after treatment with an aorto-uni-iliac endograft. Although AAA related deaths occurred throughout follow-up, after the first 30 days, none of these deaths occurred within 30 days of a re-intervention.

Re-interventions between 3 months and 3 years following repair

After 90 days 313/502 (62%) patients with repairs started remained alive. In the endovascular strategy group, between 3 months and 3 years (mid-term), the re-intervention rate decreased from 186 per 100 person years in the first 90 days to 9.5 per 100 person years in the mid-term (hazard ratio [HR] 0.05, 95% CI 0.04—0.07; $p < .001$). In the open repair group, the rate decreased from 226 per 100 person years in the first 90 days to 6.0 per 100 person years in the mid-term (HR 0.03, 95% CI 0.02—0.04; $p < .001$). In the mid-term, the re-intervention rate for life threatening conditions was 3.3 and 2.3 per 100 person years, respectively ($p = .40$) for the endovascular strategy and open repair groups.

During this period the re-intervention rates for those treated by EVAR and open repair were 12.5 and 5.0 per 100 person years, respectively ($p < .001$), but with more re-interventions for life threatening conditions in those treated by open repair ($p = .041$). In the mid-term period, for patients treated by EVAR, the commonest indication for a re-intervention was for an endograft related problem (kinking, migration, or endoleak), which occurred in 21/125 patients (17%): the re-intervention was for secondary aneurysm rupture in two cases. The patient with type 1A

Table 1. Indications for re-interventions within 90 days of randomisation.

Aneurysm related indication for 502 repairs with rupture started	Randomised to EVAR strategy ($n = 259$)	Randomised to open repair ($n = 243$)	Treated by EVAR ($n = 182$)	Treated by open repair ($n = 320$)
Access site	4	1	3	2
Abdominal compartment syndrome	7	10	2	15
Bowel ischaemia[a]	14	16	5	25
Closure open abdomen	5	5	1	9
Distal aneurysm	1	1	2	0
Endograft kinking[b]	2	0	2	0
Endoleak[c]	3	1	4	0
False aneurysm	1	0	1	0
Graft thrombosis/occlusion	3	0	1	2
Graft infection: aorta	0	2	0	2
Graft infection: femoro-femoral	2	0	2	0
Limb ischaemia	22	13	8	27
Ostomy (stoma)	1	1	1	1
Re-bleeding	3	7	1	9
Other indications				
Coronary or brain ischaemia	3	2	2	3
Miscellaneous[d]	0	3	1	2
Nutritional support	0	1	0	1
Pulmonary embolism	0	2	1	1
Renal failure	0	1	0	1
Tracheostomy for ventilator weaning	5	7	2	10
Upper GI bleed	1	5	1	5
Total re-interventions	77 in 55 patients	78 in 53 patients	40 in 29 patients	115 in 79 patients

Note. There were 27 re-interventions for life threatening indications which occurred in patients randomised to the endovascular aneurysm repair (EVAR) strategy vs. 41 in those randomised to open repair. Fifteen of these re-interventions for life threatening indications occurred in patients who received EVAR vs. 53 in those who received open repair. There were two patients in whom two indications were treated simultaneously, one treated for re-bleeding and bowel ischaemia, and one treated for type 1A endoleak and bowel ischaemia. GI = gastrointestinal.

[a] Without abdominal compartment syndrome being diagnosed.

[b] Prophylactic re-intervention to avoid graft thrombosis or occlusion.

[c] Two type 1A, two type 2.

[d] Two perforation sigmoid colon, one pleural effusion.

endoleak and secondary rupture was treated with a chimney graft to the left renal artery and a proximal cuff, whereas the patient with type 1B endoleak and secondary rupture was treated by a right limb extension. Distal aneurysm (common iliac, internal iliac, or femoral) was the next most common indication for re-intervention and occurred in both randomised groups and after treatment by both EVAR and open repair. Of note further re-interventions for bowel ischaemia only occurred after patients treated with open repair, in patients in whom abdominal compartment syndrome had not been reported earlier. Graft infection was not common during this period, with the only two cases occurring after treatment with open repair.

Re-interventions more than 3 years after repair

The data of indications for re-intervention beyond 3 years are not comprehensive, but available data suggest that there are continuing serious re-interventions, particularly in those having received EVAR.

Aortoiliac morphology and re-intervention rate

Previous reports from the IMPROVE trial had not suggested any important relationships between morphology and re-intervention rate 30 days after randomisation.[11] After 3 years, some associations begin to emerge (Table 4). There were no convincing associations between re-intervention rate and morphology after treatment by open repair. For those treated by EVAR, increasing common iliac artery diameter was associated with an increased rate of re-interventions, particularly for arterial related re-interventions, where the rate of re-intervention increased by almost 50% for each 9 mm increase in common iliac artery diameter.

After 3 years increased aneurysm neck length was associated with better survival after both procedures, but particularly after open repair, mimicking the findings previously observed at 30 days (Table S2; see Supplementary Material).

Meta-analysis of amputations within 1 year of rupture from three randomised trials

Major limb amputation for limb ischaemia is a rare re-intervention but considered to be the worst re-intervention by patients. There were eight major amputations (below knee and more proximal) in the 502 patients with repair of rupture started in the IMPROVE trial, five in those randomised to the endovascular strategy and three in

Table 2. Indications for re-interventions from 3 months to 3 years.

Aneurysm related indication for 313 repairs with rupture started who survived beyond 90 days	Randomised to EVAR strategy ($n = 167$)	Randomised to open repair ($n = 146$)	Treated by EVAR ($n = 125$)	Treated by open repair ($n = 188$)
Access site	3	1	2	2
Bowel ischaemia	2	1	0	3
Distal aneurysm	3	4	3	4
Endograft kinking[a]	2	2	4	0
Endograft migration	1	0	1	0
Endoleak[b]	14	2	16	0
False aneurysm	1	0	1	0
Graft thrombosis/occlusion	6	1	4	3
Graft infection: aorta	0	2	0	2
Graft infection: femoro-femoral	0	0	0	0
Incisional hernia	0	3	0	3
Limb ischaemia	2	2	3	1
Ostomy (stoma)	0	1	0	1
Proximal aneurysm	1	0	1	0
Secondary rupture[c]	2	0	2	0
Symptomatic adhesions	1	1	0	2
Other indications				
Nutritional support	0	1	0	1
Renal failure	1	0	1	0
Total re-interventions	39 in 27 patients	21 in 15 patients	38 in 26 patients	22 in 16 patients

Note. In those randomised to the endovascular aneurysm repair (EVAR) strategy, 17/39 of the re-interventions were for a life threatening condition vs. 7/21 in those randomised to open repair. In those having undergone EVAR 14/38 of the re-interventions were for life threatening conditions vs. 10/22 in those having undergone open repair. There were three patients in whom two indications were treated simultaneously, one for type 1A endoleak and arteriovenous fistula formation for renal failure, one for bowel ischaemia and incisional hernia, and one for type 1B endoleak and common iliac aneurysm.

[a] Prophylactic re-intervention to avoid graft thrombosis or occlusion.

[b] Four type 1A (one also had type 2), two type 1B (one also had type 2), nine type 2 only, and one type 3.

[c] One patient with a type IA endoleak and renal failure requiring dialysis and one with a type 1B endoleak.

those randomised to open repair, but seven of these amputations occurred in patients who were treated by open repair: these all occurred within 12 months of randomisation and there was one late amputation, after 3 years in the endovascular strategy group, in a patient treated by EVAR. The AJAX and ECAR trials also reported major amputations within the first year after randomisation, at a slightly higher rate than in the IMPROVE trial (three in AJAX and two in ECAR, all after open repair commenced). Meta-analysis of amputations to 1 year across the IMPROVE, AJAX, and ECAR trials by treatment received is shown in Fig. 1. The risk of amputation was much lower in those receiving EVAR (OR 0.2, 95% CI 0.05—0.88), with no evidence of heterogeneity.

Table 3. Indications for re-interventions beyond 3 years.

Aneurysm related indication for 246 repairs with rupture started who survived beyond 3 years after randomisation	Randomised to EVAR strategy ($n = 142$)	Randomised to open repair ($n = 104$)	Treated by EVAR ($n = 97$)	Treated by open repair ($n = 149$)
Access site	1	0	0	1
Bowel ischaemia	1	0	0	1
Distal aneurysm	3	1	2	2
Endoleak[a]	1	0	1	0
Incisional hernia	0	1	0	1
Limb ischaemia	1	0	1	0
Secondary rupture[b]	1	0	1	0
Other indications				
Renal failure	1	0	1	0
Total re-interventions	9 in 7 patients	2 in 2 patients	6 in 5 patients	5 in 4 patients

Note. In those randomised to the endovascular aneurysm repair (EVAR) strategy, 5/9 of the re-interventions were for a life threatening condition vs. 1/2 in those randomised to open repair. In those having undergone EVAR 4/6 of the re-interventions were for life threatening conditions vs. 2/5 in those having undergone open repair.

[a] One type 1B.

[b] Secondary to type 1A endoleak.

Table 4. The effect of aortic morphology on re-interventions in the first 3 years of follow-up.

Morphological variable	Re-interventions	Treated by EVAR ($n = 182$)	Treated by open repair ($n = 320$)	Combined ($n = 502$)
		Time to any AAA related re-intervention		
Maximum AAA diameter (per 17 mm increase)	All	0.97 (0.72—1.32) $p = .86$	0.95 (0.77—1.18) $p = .65$	0.95 (0.80—1.12) $p = .52$
	Arterial	1.02 (0.74—1.39) $p = .94$	0.85 (0.66—1.09) $p = .21$	0.90 (0.74—1.09) $p = .28$
Aneurysm neck diameter at distal renal artery (per 4 mm increase)	All	1.00 (0.77—1.30) $p = .98$	1.21 (0.99—1.49) $p = .06$	1.15 (0.98—1.35) $p = .09$
	Arterial	0.98 (0.74—1.29) $p = .88$	0.94 (0.72—1.24) $p = .67$	0.95 (0.78—1.16) $p = .63$
Aneurysm neck length (per 16 mm increase)	All	0.80 (0.58—1.10) $p = .16$	0.89 (0.72—1.10) $p = .28$	0.87 (0.73—1.03) $p = .12$
	Arterial	0.74 (0.53—1.04) $p = .08$	0.89 (0.69—1.16) $p = .40$	0.84 (0.69—1.03) $p = .09$
Neck conicality (per 1.6%, per mm length, change increase)	All	0.72 (0.45—1.15) $p = .17$	0.91 (0.74—1.11) $p = .36$	0.87 (0.72—1.06) $p = .16$
	Arterial	0.65 (0.39—1.10) $p = .11$	1.07 (0.87—1.31) $p = .52$	0.97 (0.77—1.22) $p = .80$
Proximal aneurysm neck (α) angle (per 20° increase)	All	1.01 (0.77—1.31) $p = .96$	1.05 (0.89—1.24) $p = .56$	1.04 (0.90—1.19) $p = .62$
	Arterial	0.96 (0.72—1.29) $p = .79$	0.90 (0.70—1.16) $p = .42$	0.93 (0.77—1.12) $p = .42$
Maximum common iliac diameter (per 9 mm increase)[a]	All	1.32 (1.01—1.72) $p = .041$	1.06 (0.91—1.24) $p = .45$	1.11 (0.98—1.26) $p = .11$
	Arterial	1.48 (1.13—1.93) $p = .004$	1.11 (0.92—1.35) $p = .28$	1.20 (1.04—1.39) $p = .013$

Note. Data are hazard ratio (95% CI). Aortic morphology and the risk of experiencing any re-intervention within 3 years (with multiple imputation for missing variables). Multivariate model adjusted for all six morphological variables in addition to age, sex, Hardman index, lowest recorded systolic blood pressure, and randomised group. Hazard ratios are presented per SD increase of morphological parameter. These analyses are restricted to 502 patients with confirmed rupture who received an operation by treatment received (endovascular aneurysm repair [EVAR], open or EVAR converted to open). All aneurysm related re-interventions (and only arterial re-interventions) are considered separately.

[a] Excluding eight patients with a ruptured common iliac aneurysm.

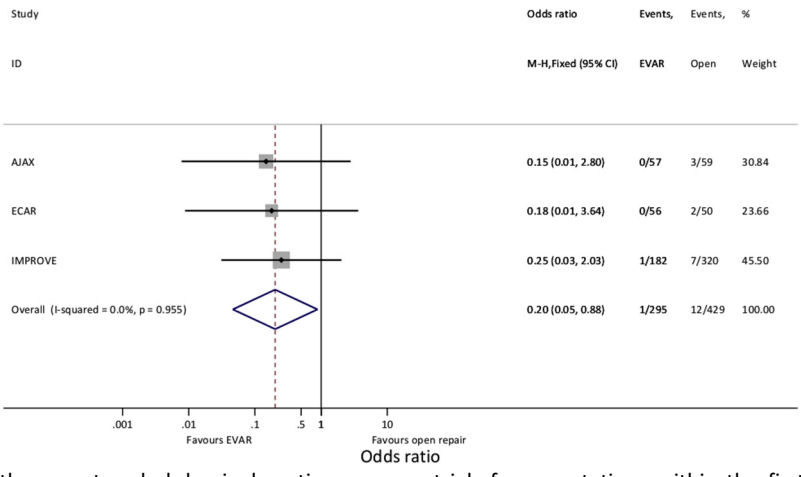

Figure 1. Meta-analysis of three ruptured abdominal aortic aneurysm trials for amputations within the first year of randomisation, by treatment received. *Note.* CI = confidence interval.

DISCUSSION

This report describes the reasons underlying the high rates of re-intervention reported after repair of ruptured AAA, detailing the re-interventions both by randomised group, as reported previously,[4] and by treatment received. Overall the percentage (~28%) of patients requiring one or more re-interventions by 3 years is twice that reported from the Medicare database.[2] Although the rates in the acute period of care (0—90 days) are highest, there is a significant rate of mid-term re-interventions in both the endovascular strategy and open repair groups, with about one third of these re-interventions needed for a life threatening condition. These mid-term re-intervention rates are over twice those reported after elective repair of large AAA.[1] It is also clear that mid-term re-intervention is needed for endograft related complications for about one in six patients after EVAR and that bowel ischaemia is a more important problem after open repair, with further mid-term re-interventions required for this condition. The present analysis indicates that the rate of arterial re-interventions is associated with increasing common iliac diameters at presentation, perhaps indicative of more extensive aneurysmal disease. The re-intervention most feared by patients is major limb amputation; fortunately, this is a rare event but individual patient data meta-analysis of the three recent European randomised trials for the management of ruptured AAA shows that amputation is five times more frequent after open repair than EVAR.

The complications and re-interventions required during the primary admission for AAA rupture have been described in the large Medicare dataset.[19] The only previous detailed reporting of midterm re-interventions comes from the Amsterdam cohort, which followed 467 patients (130 treated by EVAR, 337 by open repair).[3] The prospective data from the IMPROVE trial provide more cases with EVAR treated predominantly with bifurcated endografts, compared with the preferred use of aorto-uni-iliac endografts in the AJAX trial and Amsterdam study.[5] The finding from the Amsterdam cohort that graft infection was the commonest reason for mid-term re-intervention cannot be confirmed. Interestingly, the only two cases of graft infection after EVAR came in the acute period and were in the femoro-femoral crossover graft of patients who had been treated with an aorto-uni-iliac endograft. In the acute period abdominal compartment syndrome, bowel ischaemia and limb ischaemia were all more common after open repair. Amputation was much more common after treatment by open repair, although because this is a rare event it needed the combined data from three trials to show this. Taken together this information might suggest the direction of future quality improvement programmes, with stricter adherence to protocols to detect abdominal compartment syndrome and bowel ischaemia, and new protocols for early post-operative imaging to identify limb ischaemia and potential future problems from distal aneurysms: these latter protocols are a topic for future research and evaluation.

In the mid-term the commonest reason for re-intervention was endoleak, with about half of these being type II endoleaks: perhaps there is more enthusiasm for treating type II endoleaks after rupture than after elective repair. The next most common indication for re-intervention was distal aneurysm (in the iliac or common femoral arteries). This is likely to have contributed to the observation that increasing common iliac artery diameter was associated with an increasing rate of arterial re-interventions. There are several potential reasons for this, including focal iliac dilatation not being recognised before repair and the acceptance of a less durable seal in the common iliac artery after EVAR, to avoid internal iliac embolisation, which worsens pelvic ischaemia and prolongs the procedure. There was no other convincing evidence that other morphological parameters, including maximum aortic diameter, influenced the mid-term re-intervention rate. There were two cases of secondary rupture, both after EVAR, but neither was fatal.

The present study has some limitations. The most important of these is that data on re-interventions for the IMPROVE trial were collected from an economic perspective, with the reasons for re-intervention being collected as free text, rather than according to reporting standards. There was no separate collection of data for complications, which may not have been treated, unless they required a hospital admission. The grading of re-interventions as life threatening or not was undertaken retrospectively, following a survey of trial investigators and not included in the case record forms. Also, although the 3 month CT scans were collected in the core laboratory, there were no resources for detailed assessment of whether endograft under sizing was responsible, at least in part, for arterial re-interventions after EVAR.

In summary, this report raises two important matters. Firstly, the continuing need for mid-term re-interventions for life threatening conditions after both EVAR and open repair, at more than twice the rates after elective repair, might suggest that surveillance policies after rupture need to be more strictly enforced and more intensive than those offered after elective repair, particularly for those with open repair and/or greater common iliac diameters. Secondly, clinicians and patients view the impact of re-interventions rather differently and perhaps patient focused outcomes should be included in routine reporting metrics following rupture.

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CONFLICT OF INTEREST

None.

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APPENDIX A. SUPPLEMENTARY DATA

Supplementary data related to this article can be found at https://doi.org/10.1016/j.ejvs.2018.01.028.

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